DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018741/S-036
NDA 019555/S-033
NDA 019716/S-030

NDA SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp
Attention: Linda Birnbaum
Manager, Worldwide Regulatory Affairs
126 E. Lincoln Avenue
RY 32-461A
Rahway, NJ 07065-0900

Dear Ms. Birnbaum:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 28, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diprolene® (augmented betamethasone dipropionate) ointment, 0.05%; Diprolene® (augmented betamethasone dipropionate) cream, 0.05%; and Diprolene® (betamethasone dipropionate) lotion, 0.05%.

We also refer to our approval letter dated August 13, 2014 which contained the following error:

- text and graphics were omitted from the carton and container labeling.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 13, 2014, the date of the original approval letter.

We acknowledge receipt of your amendments dated April 5, 8, July 29, 30, August 5, 12, November 1, 2013, May 02, June 13, 16, 17, 19, July 14, 17, 23, and 24, 2014.

This "Prior Approval" supplemental new drug application provides for labeling revisions to conform to the new labeling content and format requirements for human prescription drug and biological products according to 21 CFR 201.56(d) and 201.57.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below and indicated in the enclosed labeling.

- Change the approval date from "07/2014" to "08/2014".

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions indicated, the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 018741/S-036, NDA 019555/S-033, or NDA 19716/S-030**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Strother D. Dixon, Regulatory Project Manager, at (301) 796-1015.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Acting Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TATIANA OUSSOVA
08/13/2014